

## REMARKS

### Amendments to the Claims

Claims 22-28, 36 and 37 are pending. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 22, 25 and 37 were amended. The Applicants hereby state that all amendments do not add new subject matter to the specification.

Amendment support for Claim 22 can be found at, *e.g.*, pg. 26, lines 27-30.

Amendment support for Claim 25 can be found at, *e.g.*, pg. 29, lines 26-27.

### Claim Objection

The Examiner has objected to Claim 37 for as allegedly containing an informality because the sentence lacked a period. The Applicant has amended Claim 37 to include a period at the end of the sentence. Therefore, the Applicant respectfully requests withdrawal of the claim informality against Claim 37.

### Rejection Pursuant to 35 U.S.C. § 112, ¶ 2 Indefiniteness

The Examiner has rejected Claim 25 as allegedly being indefinite pursuant to 35 U.S.C. § 112, ¶ 2 because the phrase “less than 10 MHz” includes zero. The Applicant has amended Claim 25 to recite “a frequency between 20kHz to 1 MHz.” The Applicant respectfully submit that amended Claim 25 particularly points out and distinctly claims the subject matter which the Applicant regards as his invention and respectfully requests withdrawal of the 35 U.S.C. § 112, ¶ 2 indefinite rejection against Claim 25.

**Rejection Pursuant to 35 U.S.C. § 102(a) Anticipation**

The Examiner has rejected Claims 22, 23, 26-28 and 36 as allegedly being anticipated pursuant to 35 U.S.C. § 102(e) by Herbert K. Graham, *Methods and Compositions for the Treatment of Cerebral Palsy*, U.S. Patent No. 6,939,852 (Sep. 6, 2005), hereafter “the Graham patent.”

According to *MPEP* § 2131, for a reference to anticipate a pending claim, that reference must teach each and every element of the pending claim.

Currently amended Claims 22, 23, 26-28 and 36 are directed, in part, to a method of reducing neurotransmitter release in a subdermal structure of a patient wherein step (c) comprises, in part, applying a transdermal patch comprising a pharmaceutical composition and an adhesion layer “wherein the pharmaceutical composition is incorporated into the adhesive layer.” The Graham patent does not anticipate the presently claimed transdermal patch because this patent teaches that the pharmaceutical composition is incorporated into a polymeric carrier and not directly into the adhesive layer. The present specification discusses both of these incorporation methods at pg. 26, lines 25-30, where it states:

The neurotoxin may be incorporated into a polymeric matrix that stabilizes the neurotoxin, and permits the neurotoxin to diffuse from the matrix and the patch. The neurotoxin may also be incorporated into the adhesive layer of the patch so that once the patch is applied to the skin, the neurotoxin may diffuse through the skin.

The Graham patent discloses the former incorporation method, whereas the transdermal patch of Claims 22, 23, 26-28 and 36 are directed towards the later incorporation method. As such, the transdermal patch of the Graham patent does not possess the same material structure and functional characteristics of the presently claimed transdermal patch because it does not disclose an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer. Thus, the Graham patent does not read on the presently claimed transdermal patch and the Applicants respectfully request withdrawal of the 35 U.S.C. § 102(a) rejection against Claims 22, 23, 26-28 and 36.

**Rejection Pursuant to 35 U.S.C. § 103(a) Obviousness*****I. Graham in view of Mitragotri.***

The Examiner has rejected Claims 25 and 37 as allegedly being obvious pursuant to 35 U.S.C. § 103(a) over the Graham patent in view of S. Mitragotri et al., *Ultrasound-Mediated Transdermal Protein Delivery*, 269(5225) Science 850-853 (1995), hereafter “the Mitragotri reference.”

The Examiner contends that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the method as taught by the Graham patent to include using ultrasound to enhance the penetration of high molecular weight protein across a patient's skin as taught by the Mitragotri reference because the Mitragotri reference teaches that ultrasound can promote transdermal delivery of high molecular weight proteins and the Graham patent teaches a method of reducing neurotransmitter release in a subdermal structure of a patient by applying botulinum toxin to the skin of a patient to influence acetylcholine release. See pg. 7, ¶ 2, lines 1-9, February 8, 2007 Office Action. The Applicants respectfully ask for reconsideration pursuant to 37 C.F.R. § 1.111.

According to *MPEP* § 2143.03, “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” Citing, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974).

Claims 25 and 37 are dependent on Claim 22. As discussed above, currently amended Claim 2 is directed, in part, to a transdermal patch comprising a pharmaceutical composition and an adhesion layer “wherein the pharmaceutical composition is incorporated into the adhesive layer.”

As discussed above, the Graham patent teaches a transdermal patch that a pharmaceutical composition is incorporated into a polymeric carrier. However, the Graham patent is completely silent with respect to a teaching of an incorporation method where a

pharmaceutical composition is incorporated into the adhesive layer as presently claimed. The Mitragotri reference also fails to teach the incorporation method presently claimed. As such, the Graham patent in view of the Mitragotri reference would not make the presently claimed transdermal patch obvious because neither reference alone or in combination teach or suggest the use of an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer as presently claimed. Because both references fail to teach or suggest this claim limitation a *prima facie* case of obviousness cannot be made. Therefore, the Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) obviousness rejection for Claims 25 and 37.

## ***II. Schmidt in view of Mitragotri and Glenn.***

The Examiner has rejected Claims 22-28, 36 and 37 as allegedly being obvious pursuant to 35 U.S.C. § 103(a) over Martin Schmidt, *Use of Botulinum Toxin and its Derivatives in Topical Treatment Compositions to Influence Acetylcholine-Dependent Body Functions*, DE 19852981 (May 18, 2000), hereafter “the Schmidt reference” in view of the Matragotri reference and Gregory M. Glenn and Carl R. Alving, *Use of Penetration Enhancers and Barrier Disruption Agents to Enhance the Transcutaneous Immune Response*, U.S. Patent 6,797,276 (Sep. 28, 2004), hereafter “the Glenn patent.” The Examiner contends that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of reducing neurotransmitter release of the Schmidt reference to include applying a transdermal patch as taught by the Glenn patent and include the use of ultrasound as taught by the Mitragotri reference because the Mitragotri reference teaches that ultrasound can promote transdermal delivery of high molecular weight proteins and the Glenn patent teaches a patch that is used to apply an antigen to the skin in a transdermal patch and other chemical enhancers are used in the transdermal patch. See pg. 10, ¶ 2, lines 1-8, February 8, 2007 Office Action. The Applicants respectfully ask for reconsideration pursuant to 37 C.F.R. § 1.111.

According to MPEP § 706.02, II. Reliance Upon Abstracts And Foreign Language Documents in Support of a Rejection states that “[t]o determine whether both the abstract and the underlying document are prior art, a copy of the underlying document must be obtained and

analyzed. If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection.”

The Applicants respectfully point out that the Schmidt reference is a German language document and that an English translation has not been made of record. As such, it is inappropriate for the Examiner to rely on this German-language reference as prior art. Therefore, the Applicants respectfully request that the Examiner either 1) provide an English translation of the Schmidt reference; or 2) withdrawal of the 35 U.S.C. § 103(a) obviousness rejection for Claims 22-28, 36 and 37.

### CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent.

Please use Deposit Account 01-0885 for the payment of any extension of time fees pursuant to 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

/Dean G. Stathakis/

Dean G. Stathakis, Ph.D.  
Registration No. 54,465  
Agent of Record



**ALLERGAN**

**LEGAL DEPARTMENT**

2525 Dupont Drive

Irvine, California 92612-1599

Tel: 714/246-6521

Fax: 714/246-4249